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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,504	04/21/2004	David Epstein	23239-558A (ARC-58A)	7640
30623	7590	11/05/2009		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			11/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,504	Applicant(s) EPSTEIN ET AL.	
	Examiner Richard Schnizer	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/13/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment after final rejection was received and entered on 9/15/09.

Claims 11 and 14-16 remain pending and are under consideration.

Rejections/Objections not reiterated are withdrawn.

Priority

This application claims priority to US applications 10/718,833, 10/826,077 and provisional applications 60428102, 60469628, 60464239, 60465053, 60474133, 60486580, 60489810, 60503596, and 60523935. See the amendment filed 6/9/2005. None of these applications provides an adequate written description for the genus of aptamers as claimed comprising an immunostimulatory rCGyy motif. Accordingly the filing date of the instant application is considered to be 4/21/2004.

Response to Arguments

Applicant's arguments filed 9/15/09 have been fully considered but they are not persuasive. Applicant disagrees with the Office and asserts that the '596 application discusses aptamers containing CpG motifs at pages 9 and 27, with pages 10-26 disclosing specific CpG-containing aptamers including 3 CpG motifs embraced by the instant claims. Applicant asserts that the '810 application discloses aptamers comprising CpG motifs on page 31, including a motif similar to the claimed motif. Applicant also asserts that the '133 application discloses aptamers containing CpG motifs on page 68.

However, the Office finds that none of these applications provides a written description for the genus of rCGyy motifs, as instantly claimed. None of them discloses this formula, and none of them discloses all the species embraced by the formula. The 3 aptamers from the '596 application referred to be applicant all have the same 5'-ACGTT-3' motif. The '810 application at page 31 discloses an aptamer comprising the sequence UACG-PEG-CGTA, but does not disclose an rCGyy motif, and the '133 application discloses the idea of TLR9-specific aptamers comprising CpG motifs, but does not disclose the rCGyy motif required by the instant claims. Accordingly the filing date of the instant application is considered to be 4/21/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 14-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lupold et al (US 20020119473).

Lupold et taught aptamers to PSMA that comprised the sequences 5'-ACGUU-3' or 5'-UCGAG-3'. Lupold also indicated that the aptamers were useful for the delivery of therapeutic compounds (including, but not limited to, cytotoxic compounds, immune enhancing substances and therapeutic radionuclides) to tissues or organs expressing PSMA. In the preferred embodiment, the therapeutic agent is bonded to the 5' amine of

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the aptamer. In embodiments in which cancer is the targeted disease, 5-fluorodeoxyuracil or other nucleotide analogs known to be active against tumors can be incorporated internally into existing U's within the PSMA aptamer or can be added internally or conjugated to either terminus either directly or through a linker. The conjugate may be formulated with a liposome, or a variety of pharmaceutically acceptable carriers. See abstract, Fig. 6; and paragraphs 1, 15, and 70-73. Thus Lupold taught an aptamer with the structure required by the instant claims, and so anticipates the claims.

Response to Arguments

Applicant's arguments filed 9/15/09 have been fully considered but they are not persuasive.

Applicant asserts that there is no disclosure in Lupold that the cited sequences within the PSMA nucleic acid ligands would actually bind to any target other than PSMA, or that the cited sequences would bind to such targets and stimulate an immune response. Applicant asserts that the presence of a shorter oligonucleotide sequence within a larger oligonucleotide alone is not dispositive of the ability of the shorter oligonucleotide sequence to bind a given target, and that it cannot be assumed that the cited CpG sequences would bind to a target and stimulate an immune response.

These arguments are unpersuasive. The aptamer of Lupold has the physical structure required by the claims, and so the recited function is considered to be inherent. Absent evidence to the contrary, the 5'-UCGAG-3' sequence, which is a

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species of the claimed rCGyy motif, would be bound by a TLR9 receptor and stimulate an immune response. See the instant specification at paragraph 187 which indicates that binding of CpG sequences by TLR9 receptors “triggers defense mechanisms leading to innate and ultimately acquired immune responses. For example, activation of TLR 9 in mice induces activation of antigen presenting cells, up regulation of MHC class I and II molecules and expression of important costimulatory molecules and cytokines including IL-12 and IL-23. This activation both directly and indirectly enhances B and T cell responses, including robust up regulation of the TH1 cytokine IFN-gamma.”

The office does not have the facilities for examining and comparing Applicant’s product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). The rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Tracy Vivlemore, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Richard Schnizer/
Primary Examiner, Art Unit 1635